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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,037	07/24/2001	Ben M. Dunn	UF-219XC1	2654

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/26/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,037

Applicant(s)

DUNN ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,11 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,11 and 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The following is responsive to Applicant's amendment received Feb. 5, 2003.

Claims 3, 10, 12-15 are cancelled without prejudice.

Claims 16-23 are added. Claims 1, 2, 4-9, 11 and 16-23 are currently pending.

PLEASE NOTE: This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The previous claims rejection under 35 USC 103(a) set forth in paragraphs 2-5 of the office action mailed Oct. 2, 2002 **is withdrawn** in view of applicant's amendment and the remarks contained therein.

New Ground(s) of Rejection

Claim Rejections - 35 USC § 112

1. Claims 1, 2, 4-9, 11, 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 are vague and indefinite due to the limitation directed to "preventing infection of FIV in a feline animal comprising administering to said feline an effective amount of AZT and a nucleoside analog, wherein said feline animal receives bone marrow transplantation after total body irradiation." Since a "prophylactic method" implies that the patient, in this case a cat, is not infected with FIV, then it is not clear why an invasive procedure such as total body irradiation

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and bone marrow transplantation are required. Upon reference to the specification one of ordinary skill in the art would be able to conclude that such a method would be necessary for a feline already infected and in need of treatment, but not prevention. Accordingly the metes and bounds of the patent protection desired is unclear.

Claim Rejections - 35 USC § 112

2. Claims 1, 3-6, 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preventing and treating cats infected with the strain of FIV known as FIV_{UK-8} using AZT combined with 3TC, does not reasonably provide enablement for treatment and prevention of cats infected with all strains of FIV using AZT and all types of nucleoside analogs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

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(1) The nature of the invention:

The claims are drawn to a method of treating and preventing infection of FIV in a feline animal by administering an effective amount of AZT and another nucleoside analog, wherein the feline additionally receives bone marrow transplantation after total body irradiation.

(2) The state of the prior art

According to Goodman & Gilman's, effective antiviral agents have a limited spectrum of activity and target a specific viral protein (please see page 1192; lines 13-16 of the left column). Additionally, "clinical efficacy depends achieving inhibitory concentrations at the site of infection, usually within infected cells. For example, nucleoside analogs must be taken up and phosphorylated intracellularly for activity; consequently concentration of enzymes and competing substrates influence antiviral activity in cells of different types and metabolic states." (please see page 1192, second column, (6)).

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical, chemical and viral art is high.

(5) The breadth of the claims

The claims are very broad and encompass treatment or prevention of felines infected with any type of FIV strain using AZT and any type of nucleoside analog.

(6) The amount of direction or guidance presented

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Applicant's specification provides guidance for and is only enabled for the treatment and prevention of FIV infected cats by administering AZT in combination with the nucleoside analog 3TC, wherein the particular FIV strain that is treated or prevented is FIV_{UK-8}. However, the specification provides no guidance, to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims, which, as stated above, are broad and encompass treatment or prevention of felines infected with any type of FIV strain using AZT and any type of nucleoside analog. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." Applicant's specification does not set forth a representative number of examples of nucleoside analogs which would be capable of treating or prevention FIV infection in cats. Moreover, the specification does not provide guidance to enable one of ordinary skill in the art to treat all strains of FIV known to infect cats. The only guidance available pertains to antiviral activity against FIV_{UK-8} using a combination of AZT and 3TC and BMT (see example 4) and prevention of infection in cats inoculated with FIV_{UK-8} using AZT and 3TC.

(7) The presence or absence of working examples

The examples in Applicant's specification describe treating cats infected with FIV_{UK-8} using a AZT/3TC in combination with TBI (total body irradiation) and BMT (bone marrow

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transplantation) or AZT/3TC and an protease inhibitor in combination with TBI and BMT (examples 1, 4 and 5); or preventing FIV_{UK-8} infections in cats using a combination of AZT with 3TC (please see example 2). Thus, the specification appears to enable one of ordinary skill in the art in the use of (1) AZT and 3TC (along with TBI and BMT) to treat cats infected with FIV_{UK-8} and (2) in the use of AZT and 3TC to prevent infection of FIV_{UK-8} in cats.

(8) The quantity of experimentation necessary

Since (1) the examples in the specification describe the inconsistencies in the drug sensitivities between the strains of FIV (please see page 8, lines 4-8; page 7, lines 16-18); (2) clinical efficacy depends on the ability of the nucleoside analog to achieve inhibitory concentration within an infected cell; and (2) since compound structure and activity for such pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all nucleoside analogs which would be capable of achieving inhibitory concentrations inside infected cells thereby clinically treating or preventing feline FIV infections caused by differing strains with differing drug sensitivity.

Conclusion

Claims 1, 2, 4-9, 11 and 16-23 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

June 24, 2003


DANYELLE C. JONES
PRIMARY EXAMINER